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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,404	06/08/2001	Alan D. Ford	00786-157003 / MGH-0657.3	8082

26161 7590 02/09/2006

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EXAMINER	
JARRETT, RYAN A	

ART UNIT	PAPER NUMBER
2125	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/877,404	FORD ET AL.	
	Examiner	Art Unit	
	Ryan A. Jarrett	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 61-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 61-95 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. This application is a divisional of 08/957,907, filed 10/27/97, which is a divisional of 08/665,828, filed 6/19/96.

2. It is noted that this application also appears to claim subject matter disclosed in prior Application No. 07/961,527, filed 10/15/92. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29,

2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application

transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 61-74, drawn to a drug infusion pump for use with a container containing a particular drug, the pump comprising a user interface enabling a user to program a programmable controller, wherein the user interface comprises one or more control keys that enable the user to select a drug entry from the drug library, classified in class 700, subclass 282.

II. Claims 75-95, drawn to a drug infusion pump for use with a container containing a given drug, the container including a machine-readable label, the label specifying an identifier of the given drug, the pump comprising a label reader which during use reads the contents of the machine-readable label on the container, and a processor programmed to compare information from the machine-readable label with information in the drug library to

identify an entry in the drug library that corresponds to the given drug, classified in class 604, subclass 65.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as in a drug infusion pump comprising an automatic drug selection mechanism that does not require the drug to be selected by a user, as in invention I. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

For the invention of Group I:

The container is a syringe and the drive mechanism operates the syringe. [62]

The electronically loadable memory is a non-volatile memory, or an EEPROM [63, 64].

The user interface comprises a control panel through which the user programs the programmable controller and a display screen for displaying drug entries from the drug library. [65, 66]

Each of the associated sets of drug delivery parameters includes drug concentration. [67]

Each of the associated sets of drug delivery parameters includes drug dose. [67]

Each of the associated sets of drug delivery parameters includes minimum, default, and maximum drug delivery rate. [67,68]

Each of the associated sets of drug delivery parameters includes minimum, default, and maximum bolus size. [67, 69]

The drug library contains a list of available mode options that specify units available for expressing drug delivery information, and wherein the drug infusion pump displays to the user the list of available mode options from which to make a selection; wherein the list of available mode options is selected from the group consisting of milliliters/hour, units/hour, micrograms/minute, and micrograms/kilogram/minute. [70, 71]

The drug library contains a list of names of syringe manufacturers of syringes used in the drug infusion pump, and wherein the drug infusion pump displays to the user the list of names of syringe manufactures from which to make a selection. [72]

The drug library contains a list of syringe sizes used in the drug infusion pump, and wherein said drug infusion pump displays to the user the list of syringe sizes from which to make a selection. [73]

The drug library contains a set of switchable features, each having a user selectable on and off condition, and wherein the drug infusion pump displays to the user only the features from among the set of switchable features that are in the on condition. [74]

For the invention of Group II:

The container is a syringe and the drive mechanism operates the syringe. [76]

The machine-readable label is a touch memory. [77, 87]

The configuring means also uses information from the label to configure the processor. [78, 88]

The machine-readable label includes an expiration data for the given drug and wherein the pump further comprises an internal clock indicating a current date; means for comparing the expiration date as read by the label reader to the current date as indicated by the internal clock; and means for issuing a warning if the current date is later than the expiration date; further comprising means for preventing the processor from running the drive mechanism if the current date is later than the expiration date. [79, 80, 89, 90]

The electronically loadable memory is a non-volatile memory, or an EEPROM [81, 82, 91, 92].

The pump comprises a user interface comprising a control panel through which a user responds to prompts from the processor, and a display screen for displaying information relating to drug entries from the drug library. [83, 84, 93, 94]

The pump performs a verification function by comparing information on the machine-readable label with information in the drug library. [85, 95]

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 61, 75, and 86 are generic. The elected species should correspond to the elected invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence

now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. A telephone call was made to Peter Fasse on 2/1/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

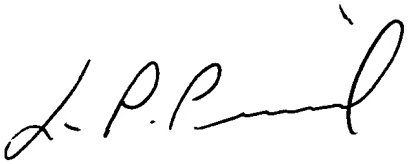
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan A. Jarrett whose telephone number is (571) 272-3742. The examiner can normally be reached on 10:00-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on (571) 272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ryan A. Jarrett
Examiner
Art Unit 2125

2/1/06
RAJ

LEO PICARD
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